SEP - 1 2011

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92

The assigned 510(k) number is : K112421

1. Submitter's identifications :

EMG TECHNOLOGY CO., LTD.
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Taiwan, R.O.C.
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510(k) owner's name :
Mr. Roger Huang
Chief Executive Officer

Contact person :
Paul Cho
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Date of Summary Preparation: Jul 7, 2011

2. Information of the Device :

Trade Name: EMG Suction Unit, Model SUA01-AXX Series
Common Name: Powered Suction Pump
Classification Name: Apparatus, Suction, Ward Use, Portable, AC-Powered
Device Class: II
Code of Federal Regulations: 21 CFR 878.4780
Product Code: JCX
Classification Panel: General & Plastic Surgery

3. Information of the 510(k) Cleared Device(Predicate Device) :

510(k) Number : K041199
Device Name: Medi-Pump Aspirator, Model 1615
Applicant: Thomas Industries

4. Device description :

The EMG Suction Unit is a compact medical suctioning device which can be powered by AC current (115V 60Hz) through the wall electric outlet at home.

The vacuum pressure of the EMG Suction Unit is to be produced through a built-in vacuum pump which is consisted of an AC motor, a cylinder, a piston connecting rod, a cup seal, an eccentric crank, an inlet valve, an outlet valve, etc. When turn on the suction unit, the motor starts to run, its shaft drive the eccentric crank which actuates the piston connecting rod moving up and down in the cylinder. When the piston is being in the down stroke, a vacuum pressure is produced in the cylinder, then air will be suctioned into the cylinder through a one-way inlet port, when the piston is being in the up stroke, it pressed out the suctioned air through another one-way outlet port to the atmosphere, these two one-way ports avoid air being suctioned from the atmosphere as well as air in cylinder being pressed back to the inlet port. When the motor keep running, a continuous vacuum pressure source through inlet port is produced.

A set of plastic cover enclose the vacuum pump, wire harness, etc. to protect the user from electrical shock and mechanical hurt hazard. The operating interface includes: a power switch, a vacuum adjusting set, a vacuum meter and a device vacuum inlet port. The vacuum adjusting set is connected to the inlet port of the vacuum pump through inner tubing, the vacuum meter and the device vacuum inlet port are connected to the vacuum adjusting set through a three-way connector and inner tubing. Device's vacuum pressure can be adjusted by tuning the knob of the vacuum adjusting set, accuracy within +/-5%. The vacuum meter display the vacuum pressure data during operation, the device vacuum inlet port provides the vacuum pressure source.

One end of a connection tubing is connected to a bacteria filter which is connected to the device vacuum inlet port, and the other end of the connection tubing is connected to a collection container. Furthermore, one end of a patient tubing is connected to the inlet port of the collection container, and the other end of the patient tubing is connected to an applied part (like suction catheter). Put the applied part to the adequate location of the patient body, then this device can start suctioning sputum or other body fluid.

The device is designed and manufactured to comply with the safety standards UL 60601-1, CAN/CSA-C22.2 No. 601.1-M90 and IEC 60601-1-2:2007, and meet the performance standard ISO 10079-1:2009.

5. Indications for Use :

The device is intended to be used to remove body fluids from a patient's airway or respiratory system. It is for use on the order of a physician only.

6. The technological characteristics comparison to Predicate Devices :

The fundamental technological characteristics of EMG Suction Unit SUA01-AXX are the same as those of the predicate device Medi-Pump Aspirator 1615, which include the following:

- Both devices have the same electrical requirement
- Both devices have the same collection bottle capacity
- Both devices have the same vacuum pump type
- Both devices contain the same overflow prevention mechanism
- Both devices are equipped with a bacterial filter to prevent contamination
- Both devices regulate vacuum by a vacuum regulator knob
- Both devices observe vacuum level with a vacuum gauge
- Both devices are equipped with a patient tubing of the same size
- Both devices are equipped with an easy-to-carry handle
- Both devices are verified to comply with electrical safety standard

The main technological difference between EMG Suction Unit SUA01-AXX and the predicate device includes the following:

- The operational specification (including vacuum range, flow rate and sound level)
- The operational power consumption
- The device outlook, dimensions and weight

Verification and validation tests contained in this submission demonstrate that the above-mentioned difference does not affect safety and effectiveness of the device or the application.

7. Discussion of Non-Clinical Tests performed for Determination of Substantial Equivalence are as the followings :

(1) Electrical safety compliance test according to UL 60601-1 conducted by accredited laboratory.

(2) EMC compliance test according to IEC 60601-1-2:2007 conducted by accredited laboratory.

(3) Performance compliance test according to ISO 10079-1:2009 conducted by manufacturer.

8. Conclusion :

In terms of the EMG Suction Unit have the same construction, function, safety, effectiveness and intended use as the 510(k) predicate device. The EMG Suction Unit is substantially equivalent to the predicate device used for this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

EMG Technology Co., Ltd.
% Underwriters Laboratories, Inc.
Mr. Marc M. Mouser
1285 Walt Whitman Road
Melville, New York 11747

SEP - 1 2011

Re: K112421
Trade/Device Name: EMG Suction Unit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: JCX
Dated: August 02, 2011
Received: August 23, 2011

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510K number (if known): K112421

Device Name: EMG Suction Unit, Model SUA01-AXX Series

Indications For Use:
The device is intended to be used to remove body fluids from a patient's airway or respiratory system. It is for use on the order of a physician only.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart CD)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112421